EXHIBIT D

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	Criminal No.
v.	21 U.S.C. §§ 331(a), 333(a)(2) and 352 (Introduction into Interstate Commerce of a Misbranded Drug)
PHARMACIA & UPJOHN COMPANY, INC. Defendant.	

INFORMATION

The United States Attorney charges that:

GENERAL ALLEGATIONS

At all times material to this Information, unless otherwise alleged:

1. **PHARMACIA & UPJOHN COMPANY, INC.** (hereinafter "**PHARMACIA INC.**") was a Delaware corporation with a principal place of business in Kalamazoo, Michigan. **PHARMACIA INC.** was a wholly owned subsidiary of Pharmacia & Upjohn LLC, the successor to Pharmacia & Upjohn Company, which was a successor of Pharmacia Corporation, all of which were acquired in April 2003 by Pfizer Inc (all of these entities and their subsidiaries hereinafter collectively "**PHARMACIA**"). During the relevant time frame, **PHARMACIA** developed, manufactured, distributed and sold pharmaceutical products nationwide and in the District of Massachusetts.

2. Prior to the April 2003 acquisition, Pharmacia Corporation and its subsidiaries, including **PHARMACIA INC.**, jointly promoted the drug Bextra with Pfizer Inc. Since April 2003, Pharmacia Corporation and Pharmacia Inc. have been wholly owned subsidiaries of Pfizer Inc.

EXHIBIT A

3. **PHARMACIA INC.** holds the United States trademarks and patents for the drug Bextra, which was distributed from Puerto Rico into interstate commerce throughout the United States, including specifically into Massachusetts, from in or about February 2002 until approximately April 2005.

The FDA and the FDCA

4. The United States Food and Drug Administration ("FDA") was the federal agency of the United States responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug and Cosmetic Act, ("FDCA"), 21 United States Code, Section 301, *et seq.*, and ensuring, among other things, that drugs intended for use in humans were safe and effective for each of their intended uses and that the labeling of such drugs bore true and accurate information.

5. The FDCA, and its implementing regulations, required that, with certain exceptions not relevant here, before a new drug could legally be introduced into interstate commerce, a sponsor of a new drug submit and obtain approval of a New Drug Application ("NDA") from the FDA.

6. The FDCA required that the NDA include proposed labeling for the proposed intended uses of the drug which included, among other things, the conditions for therapeutic use. The NDA was also required to contain, to the satisfaction of FDA, data generated in adequate and well-controlled clinical trials that demonstrated that the drug would be safe and effective when used in accordance with the proposed labeling.

7. An NDA sponsor was not permitted to promote and market a new drug until it had an approved NDA, including approval for the proposed labeling. Moreover, if approved, the

sponsor was permitted to promote and market the drug only for the medical conditions of use and dosages specified in the approved labeling. Uses not approved by the FDA, including dosages not approved in the drug's approved labeling, were known as "unapproved" or "off-label" uses.

8. The FDCA, and its implementing regulations, required the sponsor to file a Supplemental NDA ("sNDA"), in order to label or promote a drug for uses and dosages different from the conditions for use and dosage specified in the approved labeling. The sNDA was required to include a description of the newly proposed indications for use, and evidence consisting of well-controlled clinical studies, sufficient to demonstrate that the drug was safe and effective for the new use or uses. Only upon FDA approval of the sNDA could the sponsor promote the drug for the new intended use.

9. The FDCA provided that, unless otherwise exempted, a drug was misbranded if, among other things, the labeling did not contain adequate directions for use. 21 U.S.C. § 352(f)(1). Adequate directions for use could not be written for medical indications or uses for which the drug had not been approved and proven to be safe and effective through well-controlled clinical studies because unapproved uses could not be included in the labeling. Drugs that were promoted for uses that had not been approved by the FDA were deemed to be misbranded under Section 352(f)(1).

10. The FDCA prohibited the delivery for introduction and causing the delivery for introduction into interstate commerce of a misbranded drug.

The Bextra Approval Process

11. Bextra was **PHARMACIA's** trade name for the drug valdecoxib that was a so-called "Cox-2 Inhibitor." At the time Bextra first came on the market in February 2002, the

"Cox-2" class of drugs included the previously released drug Celebrex, also marketed by **PHARMACIA**, and Vioxx, manufactured and marketed by a competitor.

12. The Cox-2 class of drugs was designed to relieve various forms of pain and inflammation and was intended to offer pain relief equal to the predecessor pain relievers, but without the negative gastrointestinal side effects often associated with those drugs. Thus, for many patients, the justification for switching to a Cox-2 drug over the other available pain relievers was greater gastrointestinal safety, not better efficacy.

13. Because many of the other pain relievers, such as ibuprofen or naproxen, were available as generic and over-the-counter drugs at the time Bextra was launched, Bextra was much more expensive than the competitor drugs.

14. On or about January 15, 2001, **PHARMACIA** submitted an NDA seeking approval of Bextra, which was a new drug within the meaning of 21 U.S.C. § 321(p) and 21 C.F.R. §§ 310.3 (h)(4) and (5). In that NDA, **PHARMACIA** sought approval to market Bextra at dosages of 10 mg, 20 mg and 40 mg for the following uses:

(1) For the prevention and treatment of acute pain in adults. Preoperative administration of [Bextra] prevents or reduces post-operative pain. [Bextra] has an opioid sparing effect when used concomitantly with opioids;

(2) For the treatment of primary dysmenorrhea; and

(3) For relief of signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

The FDA Approval and Non-Approval of Bextra

15. On or about November 16, 2001, the FDA approved Bextra to treat the signs and symptoms of osteoarthritis ("OA"), adult rheumatoid arthritis ("RA") and for the treatment of primary dysmenorrhea ("PD"). **PHARMACIA** sought approval of Bextra for general acute pain,

for the preemption of the pain of surgery, and for opioid sparing, but the FDA declined to grant such approvals.

16. Moreover, although **PHARMACIA** had sought approval for the 10 mg, 20 mg and 40 mg doses for all uses, the FDA only approved the 20 mg dose twice a day as needed for PD, and the FDA only approved the 10 mg dose once a day for OA and RA (hereinafter these uses for Bextra will be referred to throughout this Information as the "Approved Uses and Dosages").

17. The FDA never approved Bextra for any use or dosage other than the Approved Uses and Dosages.

18. The FDA informed **PHARMACIA** that it was not approving Bextra for acute pain at least in part because of a safety concern about Bextra. The safety concern cited by the FDA was the results of a study of Bextra following the administration of its injectable form, parecoxib, used in patients undergoing coronary artery bypass graft surgery (the "CABG I" trial), in which the FDA noted that there was an excess of serious cardiovascular thromboembolic events in the Bextra (after parecoxib) arm of the trial.

19. In its comments to the proposed label for Bextra, the FDA also informed **PHARMACIA** that the FDA recommended against the use of 20 mg for treatment of arthritis based upon an increased potential for adverse events at higher dosages.

20. In or about October 2004, the results of a second study of Bextra and parecoxib in coronary artery bypass graft surgery ("CABG II") became public. This study showed a statistically significant increase in thromboembolic cardiovascular events in CABG patients taking Bextra following the administration of parecoxib.

21. As a result of this study, in or about November 2004, a warning was added to Bextra's product label which stated that Bextra was contraindicated for treatment of post-operative pain following CABG surgery. At the same time, the FDA required a black box warning on Bextra's label about reports of serious skin reactions, including Stevens-Johnson syndrome, in patients receiving Bextra.

22. From in or about February 2002 through April 2005, **PHARMACIA** promoted the sale of Bextra, as set forth below, for uses and dosages other than the Approved Uses and Dosages and/or with false and misleading claims of safety and efficacy and without disclosing the FDA's safety concerns.

A. PHARMACIA's Promotion of Bextra for General Acute Pain

23. **PHARMACIA** marketed Bextra for acute pain, including surgical pain, and at unapproved doses, despite the FDA's specific refusal to approve Bextra for those uses, and without disclosing to physicians, customers and others that the FDA specifically declined to approve Bextra for those uses and doses, and that the FDA's refusal was due in part to a safety concern about potential serious adverse events including cardiovascular events in some surgeries based upon the results of the CABG I study.

24. From in or about November 2001 to in or about April 2005, **PHARMACIA's** marketing team positioned Bextra for *acute* pain to differentiate Bextra's use from that of **PHARMACIA's** existing drug Celebrex, which was often used for *chronic* conditions, and to take sales from its competitor's drug Vioxx, which was used by many physicians for acute pain, among other indications. In doing so, **PHARMACIA** sought to maximize Bextra sales while avoiding cannibalizing sales of **PHARMACIA's** existing Cox-2 drug, Celebrex.

25. **PHARMACIA**'s headquarters marketing team created marketing messages and materials for the **PHARMACIA** sales force that promoted Bextra for unapproved uses and dosages, including materials that directed **PHARMACIA**'s sales force to aggressively pursue written surgical and pain management standing orders for Bextra, including for uses for which Bextra was unapproved.

26. From in or about October 2002 to January 2003, and at other times, **PHARMACIA** marketing managers commissioned market research to test new promotional visual aids for Bextra to determine, among other things, whether the visual aids delivered the "intended message" of Bextra for "acute pain."

27. For example, on or about December 5, 2002, a **PHARMACIA** marketing manager for Bextra forwarded to senior **PHARMACIA** marketing managers a market research report that concluded that "almost all physicians clearly understood the intended use of Celebrex (for chronic pain) and Bextra (for acute pain)" and noted in the cover email that the visual aid clearly communicated the "intended message" that "Celebrex is for chronic pain; Bextra is for acute or tough to treat pain."

28. On or about March 24, 2003 and thereafter, **PHARMACIA** continued to promote Bextra for such unapproved uses and dosages despite the fact that a senior **PHARMACIA** manager of market analytics notified marketing managers that "the majority" of **PHARMACIA** sales representatives surveyed were using a "chronic/acute" or "persistent/acute" distinction to describe how the physician can use Celebrex and Bextra and noted that some of the representatives surveyed voiced "discomfort" in delivering this positioning of Celebrex for chronic and Bextra for acute pain, in light of the fact that Bextra had no acute pain indication.

29. In or about March 2003, **PHARMACIA** marketing managers, in a presentation to other **PHARMACIA** marketing managers, highlighted as a success factor the fact that **PHARMACIA** had promoted Bextra for acute pain and Celebrex for chronic pain and set forth as an opportunity for improvement the "Need to Emphasize Chronic Use of Celebrex, Acute use of Bextra."

30. In or about August 2003, **PHARMACIA** commissioned a market research report to confirm that a visual aid it was preparing for sales representatives to promote Celebrex and Bextra. The report confirmed that the visual aid conveyed the message to physicians that **PHARMACIA** intended Bextra to be used for acute pain, and concluded that "[a]fter seeing the positioning statement for Bextra, virtually all physicians concluded that **PHARMACIA** was trying to differentiate Bextra as a product for acute pain."

31. In or about September 2003, **PHARMACIA** again commissioned market research to be performed to confirm that the final version of the new visual aid conveyed **PHARMACIA's** intended message for the use of Bextra. The report stated:

> More so than in other research conducted by this moderator for this team to date, physicians are starting to extract a "chronic/long-term" message for Celebrex and an "acute" message for Bextra from the visual aid materials, which will likely become more apparent over time through continued exposure to the new visual aid.

32. **PHARMACIA** continued to promote Bextra for such unapproved uses and dosages even after senior marketing managers received this market research and internal reports that indicated that the sales force was promoting Bextra for unapproved uses and dosages.

B. **PHARMACIA's Promotion of Bextra for Unapproved Uses Through Remuneration to Physicians and Purported Physician Consulting Arrangements**

33. **PHARMACIA** also promoted Bextra for unapproved use and dosages by convening so-called advisory boards, consultant meetings and other fora. **PHARMACIA** targeted physicians to participate in these meetings, as part of what **PHARMACIA** termed a "cascade of influence" in order to turn high prescribing physicians into **PHARMACIA** Cox-2 "advocates."

34. As part of this process, **PHARMACIA** conducted what it terms "Influence Mapping" in which it conducted market research to identify "influential specialists in the areas of arthritis and pain" and to provide an "Advocate Concierge" or a "High level service to aid key Advocates in managing their interaction" with **PHARMACIA**. As part of this process, **PHARMACIA** ranked key physicians in terms of their ability to influence key professional societies, regulatory agencies, guideline committees, and specialty journals.

35. For example, **PHARMACIA's** 2002 planning documents described the 2002 activities that it planned to use to disseminate its Bextra messages, including National Advisory Boards, National Steering Committee Meetings, National Consultant Meetings and Regional Consultant Meetings, all in order to "Deliver Product Messages with Data Support for Both Brands" and "Maximize Cost Synergies & ROI [Return on Investment]."

36. As part of this process, **PHARMACIA** paid targeted physicians both airfare and two to three days' accommodations at lavish resorts in the Bahamas, Virgin Islands and across the United States, and further entertained these physicians with golf, massages and other recreational activities, and also paid them an honoraria in the range of $1,000 to $2,000 for their

attendance. The number of attendees at this event often ranged from 50 to 100 health care professionals.

37. Between late 2001 and late 2003, **PHARMACIA** held almost 100 of these so-called consultant meetings and thus promoted unapproved uses and dosages of Bextra to and entertained over 5,000 health care professionals.

38. In furtherance of these plans, **PHARMACIA** paid these physicians whom it had identified as these advocates to present at lunches, dinners, and other entertainment venues, where in many instances **PHARMACIA** thereby further spread its messages about unapproved uses and dosages of Bextra.

C. **PHARMACIA's Promotion of Bextra for Surgical Pain**

39. **PHARMACIA** managers instructed their sales teams to promote Bextra for the acute pain of surgery, both pre- and post-operatively, even though they knew that Bextra was not FDA- approved for these uses, and without disclosing to physicians, customers and others that the FDA specifically declined to approve Bextra for those uses and doses, and that the FDA's refusal was due in part to a safety concern about potential serious adverse events, including cardiovascular events, in some surgeries based upon the results of the CABG I study.

40. **PHARMACIA** managers trained and directed their sales teams to seek written surgical and pain management protocols, standing orders and pathways from physicians, hospitals, and other customers for use in pre- and post-operative surgical situations.

41. **PHARMACIA** managers circulated an electronic template of a hospital-wide pain management pathway that provided for administration of Bextra for unapproved uses and at unapproved dosages and gave instructions on how to get such pathways printed on laminated

color paper and distributed in hospitals and other institutions.

42. **PHARMACIA** managers encouraged their sales representatives to promote Bextra for unapproved uses and dosages by circulating examples of written protocols obtained by other representatives that called for unapproved uses and dosages of Bextra in certain surgical and pain management settings.

43. **PHARMACIA** managers held contests to encourage the preparation and promotion of such protocols and praised and rewarded representatives who obtained such surgical and pain management protocols for unapproved uses and dosages of Bextra.

44. Consistent with these instructions and incentives, **PHARMACIA's** sales team promoted, drafted and distributed to physicians written protocols, pain management pathways and standing orders for Bextra for uses and dosages that they knew were not FDA-approved.

45. For example, in or about June or July 2002, a **PHARMACIA** sales representative in Massachusetts drafted and recommended a written protocol to an OB/GYN physician in Massachusetts calling for the unapproved use of Bextra to control pain in OB/GYN surgeries, including at unapproved dosages.

46. On or about July 19, 2002, a **PHARMACIA** Regional Manager sent an email to sales representatives in the Northeast region praising the sales representative for a "fantastic protocol" in six areas of OB/GYN surgery, each an unapproved use for Bextra.

47. On or about February 19, 2003, a **PHARMACIA** District Manager sent an email to the sales representatives in the district, with a copy to a Regional Manager that instructed the representatives to sell Bextra for pre- and post-operative pain to orthopedic surgeons, podiatrists, oral surgeons, and "anyone that uses a scalpel for a living."

48. On or about June 19, 2003, a **PHARMACIA** District Manager emailed a sample pre-operative briefing sheet to sales representatives to use, with a copy to the Regional Manager, which provided for the use of 10 mg and 20 mg of Bextra once or twice a day as part of the pre-operative surgery instructions, without any limit to Bextra's Approved Uses or Dosages.

49. In the June 19, 2003 email, a **PHARMACIA** District Manager praised the efforts of the sales representative who drafted, promoted and persuaded a physician to adopt the above briefing sheet and awarded the representative "ACE" points, which are points that could be used to select prizes such as trips, gift certificates and appliances from a **PHARMACIA** awards catalog.

50. On or about July 25, 2003, a **PHARMACIA** District Manager circulated to the Regional Manager in his district and district managers in other districts an "OPERATE FOR CASH" contest, in which sales representatives could earn ACE points by implementing Bextra written standing orders and protocols with individual orthopedic surgeons, hospital-wide, or in surgical departments.

51. On or about August 26, 2003, a **PHARMACIA** District Manager sent an email, with a copy to the Regional Manager, that instructed sales representatives to promote Bextra and Celebrex for pre- and post-operative pain, reminded them about the Operate for Cash contest, and suggested the representatives focus on "low hanging fruit," such as oral surgeons, periodontists and dentists, none of whom would have an FDA-approved use for Bextra.

D. **PHARMACIA's Off-Label Promotion of Bextra for Prevention of Deep Vein Thrombosis ("DVTs")**

52. **PHARMACIA** caused members of its sales force to promote Bextra with the claim that Bextra was effective in the surgical setting to reduce the risk of blood clots known as DVTs that can form during or after surgery. In promoting Bextra to reduce the risk of DVTs, **PHARMACIA** representatives did not disclose that the FDA specifically refused to approve Bextra for the treatment of pre- and post-operative surgical pain, and that the FDA had concluded that the safety and efficacy of Bextra for such use had not been established, including specifically that a reduction of side effects (such as DVTs) had not been shown in the studies. As **PHARMACIA** knew, there were no scientific studies showing that Bextra was safe or effective to reduce the risk of DVTs.

53. Thus, on or about April 24, 2002, a **PHARMACIA** Regional Manager sent an email to sales representatives and managers in the division, including numerous representatives and managers, and instructed them (with an attached script) to promote the use of Bextra to reduce the risk of DVTs to surgeons, even though the Regional Manager knew that Bextra had not been approved by the FDA to reduce the risk of DVTs.

54. In at least one region, **PHARMACIA** sales representatives and managers implemented this instruction and promoted Bextra to physicians to reduce the risk of DVTs during and after surgery, without disclosing to these physicians the safety concern that the FDA has raised concerning the use of Bextra in surgery, or the fact that the FDA had concluded that no decrease in the side effects of surgery such as DVTs had been shown from the use of Bextra.

E. PHARMACIA's Promotion of Bextra with False and Misleading Safety and Comparative Claims

55. **PHARMACIA** sales representatives promoted Bextra by telling physicians to replace Vioxx with Bextra even though Vioxx had an FDA-approved acute pain indication and Bextra did not; and by telling physicians that Bextra was safer and more effective than Vioxx, despite the fact that **PHARMACIA** knew there were no head-to-head studies of Bextra and Vioxx for the approved uses of Bextra that showed that Bextra was safer or more effective.

56. **PHARMACIA** sales representatives promoted Bextra with false and misleading claims of safety, including that Bextra had no dose proportional increase in hypertension and edema, that "there is not one shred of evidence showing a CV concern with Bextra," that Bextra had no cardiovascular risks unlike Vioxx, and that Bextra had placebo-like side effects.

57. For example, on or about January 16, 2004, a **PHARMACIA** Regional Manager circulated to other **PHARMACIA** managers in the Northeast a Product Action Guide that listed as core messages for the promotion of Bextra that "Vioxx's problems are not a class effect. [. . . With] Bextra there is no dose proportional response with hypertension and edema."

58. **PHARMACIA** sales representatives implemented this instruction and promoted Bextra to physicians with the claims that "Vioxx' problems are not a class effect" and "there is no dose proportional response with hypertension and edema" with Bextra, even though these claims were not proven nor supported by Bextra's label. In fact, the evidence in Bextra's label demonstrates that it does cause a dose proportional increase of hypertension and edema.

F. **PHARMACIA's Promotion of Bextra Through Falsely Claiming that Physicians Had Asked for Information About Unapproved Uses**

59. **PHARMACIA's** sales representatives also created sham physician requests for medical information about unapproved uses in order to send unsolicited information to physicians about unapproved uses and dosages of Bextra.

60. In or about June 2002, in or about November 2003, and at other times, **PHARMACIA** managers instructed members of the sales force to send out unsolicited letters known as Medical Inquiry Letters (also known as the "Medical Letter" or "Medical Inquiry Response") to, among others, groups of physicians who prescribed a lot of Vioxx. These letters were issued by **PHARMACIA** as if they were responses to physicians' unsolicited inquiries and contained medical information relating to unapproved uses and dosages of Bextra.

61. **PHARMACIA** managers instructed their sales teams to send the Medical Inquiry Letters to top Vioxx prescription writers who had not made requests for the letters, including by instructing their teams to send them to "Every Vioxx Loyalist," even though they knew it was improper to send these letters unsolicited and knew that the letters, which appeared to be a response to an unsolicited inquiry, were a disguise for improper promotion.

62. At the direction of their managers, **PHARMACIA** sales representatives sent unsolicited Medical Letters with information to support the use of Bextra for unapproved uses and dosages to physicians.

63. In the Medical Letters, **PHARMACIA** did not disclose the FDA's safety concern with the use of Bextra for unapproved uses, such as acute pain, and unapproved dosages. Nor did **PHARMACIA** disclose that the FDA raised a concern about the use of Bextra in surgery

based upon the CABG I study and the excess of serious cardiovascular thromboembolic events in the Bextra (after parecoxib) arm of the study.

G. PHARMACIA's Off-Label Promotion of Bextra By Distribution of Samples for Unapproved Uses/Doses

64. **PHARMACIA**'s sales force provided promotional samples of Bextra to surgeons and other medical prescribers who had no FDA-approved use for the Bextra samples, including by providing dosages that were unapproved for the uses for which the physicians were expected to use the samples.

65. **PHARMACIA** distributed samples of Bextra, including 20 mg samples, to physicians whom **PHARMACIA** knew would not prescribe it for approved uses or dosages, such as oral surgeons, dentists and other surgeons.

66. **PHARMACIA** allocated approximately 25% of all Bextra samples to 20 mg samples, even though **PHARMACIA** knew that the primary dysmenorrhea market (the only market for which Bextra at 20 mg was FDA-approved) was only a tiny percentage of the total potential sales (approximately 1-3%).

67. **PHARMACIA** allocated 20 mg samples to sales representatives who did not call on any type of doctor who treated primary dysmenorrhea and thus who had no FDA-approved use for 20 mg doses of Bextra.

68. **PHARMACIA** used a national computer program to direct the sales force on how to utilize these free samples, which instructed sales representatives to increase use of 20 mg samples for certain physicians, such as rheumatologists and orthopaedic surgeons, even though these physicians had no approved use for such samples.

H. **Use of Purportedly Independent Continuing Medical Education to Promote Bextra for Unapproved Uses and Dosages**

69. **PHARMACIA** also funded purportedly independent continuing medical education programs ("CME") with the stated purpose of disseminating messages promoting Bextra for unapproved uses, including specifically for acute pain and surgical pain.

70. **PHARMACIA** accomplished this by incorporating CME planning into its marketing messaging strategy for Bextra. Among the practices **PHARMACIA** employed was to hire advertising agencies to prepare standard promotional slides for Bextra, and then had these slides certified by other vendors as "CME." It then caused these Bextra slide sets to be distributed to the "advocates" it had trained so that they could use the slides for CME events as well.

71. **PHARMACIA's** headquarters-based marketing teams also created annual medical education plans in which they reflected the intention to "leverage CME" to provide data beyond the approved label. The plans listed the specific messages for Bextra to be relayed, including messages such as Bextra power for "Acute pain, Opiod-sparing."

72. In 2002 alone, **PHARMACIA** funded CME programs for Bextra designed to reach 30,000 physicians, including in many instances with the unapproved messages.

I. **Promotion of Bextra for Unapproved Uses and Dosages by Supporting and Drafting Publications**

73. **PHARMACIA** also promoted Bextra for unapproved uses and dosages through a "publication strategy" whereby **PHARMACIA** initiated, funded, sponsored and sometimes drafted or hired medical writer vendors to draft articles about Bextra for unapproved uses and dosages in order to promote these uses and dosages, without always appropriately disclosing

PHARMACIA's role in the process.

74. **PHARMACIA** implemented a "manuscript development" process whereby a core team at **PHARMACIA** would plan potential publications and recruit authors for them. Some of those listed in the publication plans were listed with authors as "TBD" (to be determined) or "TBC" (to be chosen).

75. **PHARMACIA** also created an overall list of its goals for this process, which included relaying unapproved messages for Bextra such as "Acute Pain: BEXTRA Provides Rapid, Powerful Pain Relief in surgical pain."

COUNT ONE

(Introduction into Interstate Commerce of a Misbranded Drug: 21 U.S.C. §§ 331(a), 333(a)(2) & 352(f))

76. The allegations contained in paragraphs 1 through 75 are realleged and incorporated herein as if set forth in full.

77. Between February 2002 and April 2005, in the District of Massachusetts and elsewhere, the defendant,

PHARMACIA & UPJOHN COMPANY, INC.

with intent to defraud and mislead, did introduce, deliver for introduction, and cause the introduction into interstate commerce, into Massachusetts and elsewhere, quantities of Bextra, a drug within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(g), which was intended for use for the treatment of acute pain, surgical pain, other unapproved uses, and at unapproved dosages, which was misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that it lacked adequate directions for such uses.

All in violation of 21 U.S.C. §§ 331(a), 333(a)(2), and 352(f)(1).

FORFEITURE ALLEGATIONS

1. As a result of the violation of Title 21, United States Code, Sections 331(a), 333(a)(2), and 352(f)(l) set forth in this information, defendant,

PHARMACIA & UPJOHN COMPANY, INC.

shall forfeit to the United States of America any quantities of Bextra, which between February, 2002, and April 5, 2005, were misbranded when introduced into or while in interstate commerce, or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of Title 21, United States Code, Section 331, be introduced into interstate commerce.

2. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

(a) cannot be located upon the exercise of due diligence;

(b) has been transferred or sold to, or deposited with, a third party;

(c) has been placed beyond the jurisdiction of the Court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture, that is $105,000,000.

All pursuant to Title 21, United States Code, Sections 334 and 853 and Title 28, United Stales Code, Section 246l(c).

MICHAEL K. LOUCKS
ACTING UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS

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